

The following action is being sent in response to the Interview with applicant's representative Stephanie Wardwell on September 23<sup>rd</sup> 2010, to present the correct WIPO publication number cited in the previous office action.

### **DETAILED ACTION**

#### ***Status of Claims***

Claims 1-19 are currently pending, claims 2-5, 7, 11-13, and 16-19 have been withdrawn due to the election requirement filed on July 9<sup>th</sup> 2010.

#### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-17 and the species of compound 2 (formula IIII and western blotting in the reply filed on July 9<sup>th</sup> 2010 is acknowledged.

#### ***Information Disclosure Statement***

The Information Disclosure Statements (IDS)s, filed by applicant on October 18<sup>th</sup> 2006, and May 12<sup>th</sup> 2006 have been considered by the examiner in the present case.

#### ***Claim Rejections - 35 USC § 101/112***

Claims 1, 6, 8-10 provide for the use of an index of protein expression, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1, 6, 8-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

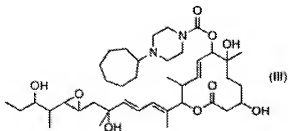
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1, 6, 8-10, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cover, C.M., et al., (JBC, 1998) in view of Fukada et al., International Patent Application Publication WO 03/099813 (cited in the IDS) as evidenced by U.S. Patent Application Publication 2006/0009439 serving as an official English translation of the International Application.**

Cover teaches methods to identify inhibitors of breast cancer and their mode of action. (See title.) Cover teaches assay methods involving treating cancer cells with compounds such as Indole-3-carbinol (I3C) and analyzing the effects upon protein expression in the cells by Western blotting. (See page 3840 paragraph 2 and page 3840, paragraph 2.) Cover teaches monitoring the expression of the specific proteins cyclin E and Rb using Western blotting (See page 3840 paragraph 2, and figures 3-4.) Cover teaches that cyclin E expression is increased in cancer cell lines and pRB is increased. (See page 3839, paragraph 3.) Cover teaches that the endogenous Rb protein level is decreased in (I3C) treated cells, which causes cell cycle arrest stopping the growth of the cancer cells. (See page 3842, paragraph 3, page 3846 paragraph 6, and figure 4.)

Cover does not teach assaying the currently elected species of compound 2 (forumula III) depicted below.



Fukada et al teaches anticancer compounds for treating cancer. (See abstract.)  
Fukada teaches the specific compound 2 (above). (See page 216 of the WIPO publication and/or example 45 page 56 of 2006/0009439.)

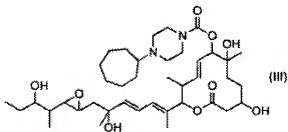
It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use known methods of identifying and determining the mode of action of cancer drugs as taught by Cover to investigate the mode of action of a known anticancer drug such as those taught by Fukada in order to understand how the drug functions to inhibit cancer. The skilled artisan would have expected this combination to function as Cover teaches that cyclin E, Rb and the expression of a number of proteins are regulated by anticancer drugs and that these levels change depending on how and if the drug functions to suppress the cancer. Using the compounds of Fukada in the method of Cover is merely the application of a known technique to a known drug.

**Claims 1, 6, 8-10, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandor, V., et al., (British Journal of Cancer, 2000) in view of Fukada et al., International Patent Application Publication WO 03/099813 (cited in**

**the IDS) as evidenced by U.S. Patent Application Publication 2006/0009439 serving as an official English translation of the International Application.**

Sandor teaches methods to identify inhibitors of cancer and their mode of action. (See title.) Sandor teaches assay methods involving treating cancer cells with compounds such as FR901228 and analyzing the effects upon protein expression in the cells by Western blotting. (See page 818 paragraph 2 and page 3840, paragraph 2.) Sandor teaches monitoring the expression of the specific proteins cyclin E and Rb using Western blotting (See page 818 paragraph 4.) Sandor teaches that cyclin E expression is decreased upon exposure to the anticancer drug FR01228, stopping the growth of the cancer cells. (See abstract.)

Sandor does not teach assaying the currently elected species of compound 2 (formula III) depicted below.



Fukada et al teaches anticancer compounds for treating cancer. (See abstract.) Fukada teaches the specific compound 2 (above). (See page 216 of the WIPO publication and/or example 45 page 56 of 2006/0009439.)

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use known methods of identifying and determining the mode of action of cancer drugs as taught by Sandor to investigate the mode of action of a known

anticancer drug such as those taught by Fukada in order to understand how the drug functions to inhibit cancer. The skilled artisan would have expected this combination to function as Sandor teaches that cyclin E expression is upregulated by anticancer drugs causing the cancer cells to stop or die. Using the compounds of Fukada in the method of Cover is merely the application of a known technique to a known drug.

### ***Conclusion***

No claims are currently allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LANCE RIDER whose telephone number is (571)270-1337. The examiner can normally be reached on M-F 11-12 and 1-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LANCE RIDER/  
Examiner, Art Unit 1618

/Michael G. Hartley/  
Supervisory Patent Examiner, Art  
Unit 1618